

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: Civil Action No. MDL 2327
ETHICON, INC., PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION**

**Master File No. 2:12-MD-02327
Southern District of West Virginia
Charleston Division**

**SECANT’S REPLY IN SUPPORT OF ITS MOTION TO STAY ENFORCEMENT OF
PLAINTIFF’S SUBPOENA PENDING A DETERMINATION OF THE
APPLICABILITY OF THE BAAA TO SECANT**

Defendants Secant Medical, Inc., Secant Medical LLC, and Prodesco, Inc. (collectively “Secant”) submit this Reply to highlight the inaccuracies in Plaintiffs’ Opposition and emphasize Secant’s position on discovery. Plaintiffs’ purported justification for discovery under the Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1601-06 (“BAAA” or “Act”), is based on incorrect assumptions and a misreading of the Act. For the reasons below, and as set forth in Secant’s opening Memorandum, this Court should grant Secant’s Motion for a Stay until the BAAA’s applicability to Secant has been determined through Secant’s Motion to Dismiss:

- First, Plaintiffs argue that the Biomaterials Access Assurance Act of 1998, 21 U.S.C. §§ 1601-06 (“BAAA” or “Act”), “specifically permits” the requested discovery of Secant. (Pls.’ Opp. at 4.) Plaintiffs are mistaken. In fact, the BAAA expressly *prohibits* discovery once a motion to dismiss is filed, except under limited circumstances not present here. *See* 21 U.S.C. § 1605(c). The BAAA’s prohibition on discovery is explained below.
- Second, Plaintiffs argue that the document requests in the contested subpoena at issue here are “the same” as those in the notice of deposition issued in *Hansen*, a

Pennsylvania state case. (Pls.' Opp. at 5.) Again, Plaintiffs are mistaken. The discovery sought here is quite different from that at issue in *Hansen*. Compare Ex. A to Pls.' Opp. (subpoena), with Ex. E to Pls.' Opp. (*Hansen* Notice of Deposition).¹

- Third, Plaintiffs argue that an order directing Secant to produce discovery has been issued in the Pennsylvania state court cases. (Pls.' Opp. at 5.) Once again, Plaintiffs are mistaken. The documents Plaintiffs cite—a court order denying Secant's preliminary objections without prejudice and a case management order in a different case—do not order Secant to comply with any discovery requests.

Aside from correcting these inaccuracies in Plaintiffs' Opposition and providing the further explanation below concerning the BAAA's prohibition on discovery, Secant rests on its opening Memorandum and respectfully requests that the Court stay enforcement of Plaintiff's Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises pending a determination of the applicability of the BAAA.

THE BAAA EXPRESSLY PROHIBITS THE REQUESTED DISCOVERY

As noted above, the BAAA prohibits the discovery that Plaintiffs seek. The Act expressly provides that discovery should be halted pending a ruling on a defendant's motion to dismiss. The Act states in relevant part:

- (1) Effect of motion to dismiss on discovery.
- (A) In general. Except as provided in subparagraph (B), if a defendant files a motion to dismiss under [§ 1605(a)], ***no discovery shall be permitted in connection with the action that is the subject of the motion***, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, ***until such time as the court rules on the motion to dismiss***.

¹ Secant is currently addressing with plaintiffs in the *Hansen* case pending in the Philadelphia County Court of Common Pleas the scope of discovery, if any, for the deposition as noticed. Secant will agree to make available to plaintiffs in the MDL any discovery that the parties are able to agree on in the *Hansen* matter on the same schedule as such discovery, if any, is made available in *Hansen*.

- (B) Discovery. If a defendant files a motion to dismiss under [§ 1605(a)(3)] on the grounds that it did not furnish raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to—
- (i) the pending motion to dismiss; or
 - (ii) the jurisdiction of the court.

21 U.S.C. § 1605(c)(1) (emphasis added) (incorrectly cited in Pls.’ Opp. as § 1605(d)).² As emphasized above, the general rule is clear: *no* discovery is permitted once a party files a motion to dismiss until the court rules on that motion. This general rule prohibiting discovery is subject to only two exceptions: (1) “discovery necessary to determine a motion to dismiss for lack of jurisdiction,” and (2) discovery necessary to decide a motion to dismiss filed under 21 U.S.C. § 1605(a)(3). Neither exception applies here.

First, Secant has *not* moved to dismiss Plaintiffs’ claims on the basis that the Court lacks jurisdiction. In fact, Secant *never* has disputed that this Court has jurisdiction.³ Instead, Secant moves to dismiss Plaintiffs’ claims because it is immune from liability under the BAAA. Immunity under the BAAA is a statutory right, *not* a jurisdictional issue for purposes of 21 U.S.C. § 1605(c)(1). Any interpretation of the term “jurisdiction” in § 1605(c)(1) that permitted the broad discovery sought by Plaintiffs here would be completely inconsistent with the BAAA’s

² Plaintiffs also incorrectly attribute their quotation from 21 U.S.C. § 1605(d)(3) to § 1605(c)(3). (Pls.’ Opp. at 4.) Plaintiffs’ incorrect attribution is significant. Section 1605(c)—the section to which Plaintiffs cite—governs discovery in the context of a motion to dismiss, while § 1605(d)—the section from which Plaintiffs actually quote—governs discovery in the context of a motion for summary judgment (or a motion to dismiss that is treated as a motion for summary judgment). In the context of a motion to dismiss, § 1605(d)(3) *limits* the scope of discovery permitted under § 1605(c)(1)(B), a discovery exception discussed in the text above that does not even apply here.

³ Not even Plaintiffs can seriously dispute the Court’s jurisdiction. Before the Judicial Panel on Multidistrict Litigation transferred the *Hammons* case to this Court, Judge Joyner specifically ruled that the Eastern District of Pennsylvania had diversity jurisdiction. *See Hammons*, ECF Doc. No. 17 at 1 n.1 (ruling that court “clearly has subject matter jurisdiction over this matter . . . pursuant to 28 U.S.C. § 1332” notwithstanding plaintiff’s argument that Ethicon improperly removed her case in violation of the “forum defendant” provision of 28 U.S.C. § 1441(b)(2)) (citing *Korea Exchange v. Trackwise Sales Corp.*, 66 F.3d 46, 50-51 (3rd Cir. 1995) (holding that forum defendant’s erroneous removal did not deprive district court of diversity jurisdiction because “invocation of the removal machinery by a citizen of the forum state, while error, is not a ‘jurisdictional’ defect under relevant Supreme Court precedent”).

general rule prohibiting discovery and would render meaningless § 1605(c)(1)(B) and the very *limited* discovery allowed by this second exception to that general rule. Accordingly, the first exception to the BAAA's general rule prohibiting discovery does not apply.

Second, Secant did not file its motion to dismiss “under” 21 U.S.C. § 1605(a)(3). This section provides that a defendant may move to dismiss a plaintiff's complaint on the ground that it is a biomaterials supplier and is not liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications. *See id.* Plaintiffs, however, do *not* allege that the bulk mesh used to make the implanted medical devices at issue here failed to meet Ethicon's contractual requirements or specifications. Rather, Plaintiffs dispute that Secant is a biomaterials supplier and contend instead that Secant is a “manufacturer” of Ethicon's devices for purposes of the BAAA. (*See, e.g.*, Pls.' Mot. to Remand in *Hammons*, at 15-17.) Given Plaintiffs' allegations, Secant moved to dismiss Plaintiffs' claims on the grounds that it is a biomaterials supplier and is neither a manufacturer nor a seller of Ethicon's implants. While Secant also noted the absence of any allegations that the bulk mesh it supplied failed to meet Ethicon's contractual requirements or specifications, Secant's argument does not transform its motion to dismiss as one arising “under” 21 U.S.C. § 1605(a)(3). Because Secant's compliance with Ethicon's contractual requirements and specification is *not* disputed in this case, Plaintiffs' requested discovery is not permitted under 21 U.S.C. §§ 1605(c)(1)(B) or 1605(d)(3).

In addition, not staying enforcement of Plaintiffs' subpoena would frustrate Congress' intent in enacting the BAAA. Congress found that biomaterials suppliers “have ceased supplying certain raw materials and component parts for use in medical devices” because of “concerns about the costs of . . . litigation.” *Id.* § 1601(8). Based on this finding, Congress

determined that “immediate action is needed . . . to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.” *Id.* § 1601(15)(B). The BAAA’s express limitations on discovery serve to advance Congress’ intent to minimize litigation costs incurred by biomaterials suppliers like Secant.

For the reasons stated herein, as well as in Secant's moving papers, this Court should grant Secant's Motion to Stay Enforcement of Plaintiffs’ Subpoena.

Respectfully submitted,

TUCKER LAW GROUP, LLC

Dated: November 25, 2013

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CERTIFICATE OF SERVICE

I, V. Amanda Witts, Esquire, hereby certify that on October 28, 2013, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

TUCKER LAW GROUP, LLC

Dated: November 25, 2013

/s/ V. Amanda Witts

V. Amanda Witts, Esquire